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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/147,770	04/28/1999	PIERO DEL SOLDATO	P8907-9002	2174

7590 05/07/2003

ARENT FOR KINTNER PLOTKIN & KAHN
1050 Connecticut Avenue N W Suite 600
Washington, DC 20036-5339

EXAMINER

TRAVERS, RUSSELL S

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 05/07/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

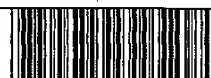
Office Action Summary

Application No.
09/147,770

Applicant(s)
Del Soldato et al

Examiner
R.S. Travers J.D., Ph.D.

Art Unit
1617



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 21, 2003
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, and 5-20 is/are pending in the application.
- 4a) Of the above, claim(s) 6-8 and 11-20 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 10 is/are allowed.
- 6) ☒ Claim(s) 1, 2, 5, and 9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other: _____

Art Unit:

The response filed April 21, 2003 and declaration filed August 7, 2002 have been received and entered into the file.

Applicant's arguments filed April 21, 2003 have been fully considered but they are not deemed to be persuasive.

Claims 1-2, and 5-20 are presented for examination.

Applicant's election without traverse of Group I, claims 1-5 in Paper No. 10 is acknowledged.

Claims 6-8, and 11-20 reading on non-elected subject matter are withdrawn from consideration. Claims 1-2, 5, 9 and 10 will be examined to the extent they read on the elected subject matter.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Art Unit:

Claim 10 is rejected under 35 U.S.C. § 103 as being unpatentable over Merck Index #4852, Morikawa et al, Persson et al and Chung et al.

Merck Index #4852 teach indomethacin as old and well known in combination with various pharmaceutical carriers and excipients in a dosage form. This medicament is taught as useful for treating inflammation. Morikawa et al teach indomethacin as old and well known in combination with various pharmaceutical carriers and excipients in a dosage form. Persson et al and Chung et al Morikawa et al teach NO donors as old and well known in combination with various pharmaceutical carriers and excipients in a dosage form. Nitric oxide donors are taught by Persson et al and Chung et al as useful for increasing the time to micturition, and increasing bladder pressure threshold. These medicament are taught individually as useful for increasing the time to micturition, and increasing bladder pressure threshold. Compounds taught as useful for increasing the time to micturition, and increasing bladder pressure would have been seen as useful for treating urinary incontinence by the skilled artisan.

1) the recitation of those medicaments set forth in claim 10

The skilled artisan, possessing a compound for a therapeutic use possesses that compounds analogs, homologs, isomers, bioisosteres, salts, acids and esters for the same use. To employ an analog, homolog, isomer, bioisostere, salts acid and ester for the same use therapeutic use would have been obvious to the skilled artisan.

Art Unit:

Prior art use for the same therapeutic purpose would have motivated the skilled artisan to employ indomethacin esters to the same therapeutic use and enjoy a reasonable expectation of therapeutic success.

Claims 1-2 and 5 are rejected under 35 U.S.C. § 103 as being unpatentable over Scherrer et al and Matji et al, in view of Persson et al and Chung et al, of record.

Scherrer et al and Matji et al teach those compounds residing in the instant claims 1, 2 and 5 as old and well known in combination with various pharmaceutical carriers and excipients in a dosage form. These medicaments are taught as useful for treating inflammation. Persson et al and Chung et al teach NO donors as old and well known in combination with various pharmaceutical carriers and excipients in a dosage form. Nitric oxide donors are taught by Persson et al and Chung et al as useful for increasing the time to micturition, and increasing bladder pressure threshold. These medicament are taught individually as useful for increasing the time to micturition, and increasing bladder pressure threshold. Compounds taught as useful for increasing the time to micturition, and increasing bladder pressure would have been seen as useful for treating urinary incontinence by the skilled artisan. Claims 1-2 and 5, and the primary references, differ as to:

- 1) the recitation of those medicaments set forth in claims 1, 2 and 5,

Art Unit:

The skilled artisan, possessing a compound for a therapeutic use possesses that compounds analogs, homologs, isomers, bioisosteres, salts, acids and esters for the same use. To employ an analog, homolog, isomer, bioisostere, salts acid and ester for the same use therapeutic use would have been obvious to the skilled artisan. Prior art use for the same therapeutic purpose would have motivated the skilled artisan to employ indomethacin esters to the same therapeutic use and enjoy a reasonable expectation of therapeutic success.

It is generally considered prima facie obvious to combine two compounds each of which is taught by the prior art to be useful for the same purpose, in order to form a composition which is to be used for the very same purpose. The idea for combining them flows logically from their having been used individually in the prior art. As shown by the recited teachings, the instant claims define nothing more than the concomitant use of conventional anti-detrusor agents. It would follow that the recited claims define prima facie obvious subject matter. Cf. In re Kerhoven, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980).

RESPONSE TO ARGUMENTS

Newly presented rejection renders the instant rebuttal arguments moot.

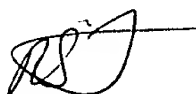
Applicants declaration filed under 37 CFR 1.132 has been reconsidered, and is found convincing.

Art Unit:

As stated above, the instant claims read on analogs, homologs, isomers, bioisosteres, salts, acids and esters known for the same therapeutic use claimed herein. The skilled artisan possessing the core compounds for the same therapeutic purpose would have motivated the skilled artisan to employ indomethacin esters to the same therapeutic use enjoying a reasonable expectation of therapeutic success.

Applicant's attention is drawn to In re Dillon, 16 USPQ2nd 1897 at 1900 (CAFC 1990). The court sitting in banc ruled that the recitation of a new utility for an old and well known composition does not render that composition new.

Any inquiry concerning this communication should be directed to Russell Travers at telephone number (703) 308-4603.



Russell Travers J.D., Ph.D.
Primary Examiner
Art Unit 1617